



AIDS HOME TEST KITS

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AIDS HOME TEST KITS

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- Test yourself with confidence using the same test your doctor uses—but in the privacy of your home!~

— Instructions for a proposed AIDS home test kit

I. INTRODUCTION

Human immunodeficiency virus disease is the most serious communicable epidemic in contemporary times. The challenges HIV disease presents are formidable: it cannot yet be cured or prevented. Carriers are chronically infectious, and those at greatest risk are some of our citizens most vulnerable to social discrimination and private prejudice. By the end of 1991 there were 200,000 reported cases of AIDS in the United States and public health officials estimate that another one million people are currently HIV-infected. The overwhelming majority—estimates range from 75% to 90% — of those carrying the HIV virus are unaware that they are infected.

The focal point of the many controversies surrounding AIDS is testing. Once a test for antibodies to the AIDS virus was developed, the issue of mandatory testing or screening immediately arose. Those opposed to wide-scale testing, convinced confidentiality could not be maintained, cited concerns of privacy, liberty, and social and economic discrimination. Others asserted that protection of the communal well-being demanded compulsory testing. While routine testing of the blood supply went unchallenged, calls for a far-reaching authoritarian public health response lost to the voluntarist consensus. Public health officials and legislatures concluded that compulsory testing, whether mass or targeted, would be prohibitively expensive, that it would lead to invidious discrimination, particularly against homosexuals and drug users, and that the history of public health measures demonstrated most coercive measures to be of dubious efficacy.

Thus, with federal funding and support we created a network of free, confidential and anonymous testing centers. Thirty-six states have enacted informed consent and confidentiality legislation governing AIDS testing.¹ To address concerns of confidentiality, there is no federal requirement to report seropositive results to public health officials; data is only collected on the actual onset of AIDS. Underlying these voluntarist strategies is the belief that more people will be tested under these conditions, benefiting both individuals and the public welfare.

Given the emphasis on private, confidential and voluntary testing, the idea of an AIDS home test kit was inevitable. What could be more private, confidential and voluntary (and profitable) than buying a test kit at a drug store to take home and use? In 1986 the Food and Drug Administration (FDA) began receiving applications for various kinds of AIDS home test kits and immediately found itself at the center of a political maelstrom. Congressional subcommittees, AIDS activists, the gay community, doctors and scientists were quickly pitted against several entrepreneurs interested in bringing these products to market. FDA responded by refusing to even consider and evaluate any applications for AIDS home test kits for several years. Finally, in 1990 the FDA effectively reversed this policy and with little controversy began accepting applications for the kits.

In this paper I want to assess the FDA's and the public's evolving response to the idea of AIDS home tests. Additionally, what is the FDA's role in a public health crisis such as the AIDS epidemic? What are legitimate criteria for FDA to weigh when evaluating a product such as an AIDS home test kit? More generally, are AIDS home test kits good public policy? I begin by sketching a brief history of the FDA's regulation of the product. Next I discuss the various arguments for and against an AIDS home test. I conclude with an analysis of the FDA's role in a debate such as this and some thoughts on the politics of AIDS.

I Burns, Scott, 'Testing, Disclosure, and the Right to Privacy, *AIDS Law Today*, ed. Burris, 115. 121 (1993).

Any debate about the AIDS problem requires an understanding of what the problem is, and on that front there is frequent disagreement. Like epidemics throughout history, HIV disease is as much a political, cultural and social phenomenon as it is a biological one. Thus, it is hardly surprising that the AIDS debate in this country is emotionally and politically charged on all sides. For instance, partly because the majority of the early victims were homosexual men, the disease acquired a devastating stigma, and many people continue to conceptualize AIDS as divine retribution for a sinful lifestyle. On the other side, the gay community vigorously and successfully politicized the public discourse as a tactical measure in the fight against AIDS. For both groups, AIDS holds special significance. Any discussion of AIDS policy must bear in mind that AIDS has become more than a medical condition.

II. FDA REGULATION OF AIDS HOME TEST KITS

Home Test Kits: There are two kinds of AIDS home test kits. The first is known as a home performance kit and is similar to the home pregnancy tests. The user conducts the test and interprets the results in his or her home. No such legitimate devices have appeared on the market, although the technology for such a home test is on the horizon. The second category consists of blood collection kits. The kits contain a skin

disinfectant, a lancet for self-blood letting, a capillary tube or other collection medium, cotton or gauze, a bandage, and an instruction booklet. The user draws a blood sample which he or she then sends in a supplied mailing package to a laboratory where the blood is tested for the presence of antibodies to the HIV virus. The user later phones the testing center using a coded number to obtain the results and counseling. The AIDS home tests

2 The FDA is nearing completion of the review process for an AIDS test developed by Epitepe which uses saliva rather than blood. *The Gray Society* (November 15, 1993).

proposed so far have been blood collection kits and these are what I will be discussing unless otherwise noted.

Regulatory Framework and History: AIDS home test kits are medical devices subject to FDA regulation under the Medical Device Amendments of 1976 to the Food, Drug and Cosmetics Act. In 1987 the FDA classified AIDS home test kits as Class III medical devices which require clinical testing for safety and effectiveness and premarket approval (PMA) prior to marketing.³ As interest in the home diagnostic kits grew, the FDA transferred authority over them from the Center for Devices and Radiological Health to the Center for Biologics Evaluation and Research which was already deeply involved in the AIDS epidemic.

In 1987 a company called Universal Health Laboratories submitted a PMA for a blood collection kit. By this time, there was pressure on FDA from several fronts, including Congress and AIDS activists, to keep AIDS home test kits off the market. Concerns were voiced about test performance and safety, confidentiality, and counseling. In response, the FDA issued five draft points to consider for any applicants seeking PMAs for AIDS diagnostic kits.

- (1) The kits must be labeled and marketed for professional use only within a comprehensive health care environment.
- (2) The kit must provide for blood drawing by a licensed authority.
- (3) A licensed screening test for HIV antibodies must be used. When the screening test yields a positive result, it must be confirmed using a more specific, licensed test such as the Western Blot.
- (4) The kit's instructions must be the equivalent of the package insert for the licensed antibody test used.
- (5) All test results must be reported to a professional health care provider for interpretation, reporting and counseling.⁴

Depending on your position, the FDA was either being cautious or imposing a *de facto* ban on home test kits for AIDS. Relying on these draft points and concerns raised by advisory groups and interested parties, in March 1988 the FDA declined to file Universal

~ Unapproved AIDS Home Test Kits, FDA Talk Paper No. T87-35 (July 23, 1987).

~ 53 Fed. Reg. 46118 (November 16, 1988).

Health Laboratories' PMA application, thus refusing to even look at the data and research. The FDA did eventually announce that hearings would be held on the issue, a few weeks after a House subcommittee hearing on the same topic.⁵

The FDA and congressional hearings were primarily opportunities to test the political winds. The majority of the witnesses representing the FDA, AIDS clinics, and the medical profession opposed the AIDS home test kits for a variety of reasons, as discussed below. In fact, Representative Ron Wyden convened the subcommittee hearing because he was dismayed to hear that the FDA may reverse its opposition to AIDS home testing kits.⁶ The only vigorous dissent to the FDA's restrictions on the diagnostic kits came from interested entrepreneurs such as Eliot Millenson, founder of Universal Health Laboratories. FDA took no action on the kits for the next year.

Then, in the spring of 1990 the FDA announced that it would welcome applications for AIDS home test kits? Although the agency said the five criteria listed above were still valid, the implicit message was that the FDA was at least willing to look at the data and research. At the same time the FDA reached a settlement in a lawsuit filed by Universal Health Laboratories.⁸ As part of the settlement, the company's PMA was filed and evaluated. In August 1990, however, the FDA denied Universal Health Laboratories a PMA on a number of grounds, as discussed below.⁹

As of this date, the FDA has not approved an AIDS home test kit.

III. THE DEBATE OVER AIDS HOME TEST KITS

Test Performance and Safety: Can an AIDS test be safely and effectively used in the home by nonprofessionals? The answer depends largely on what is meant by an AIDS home test. If the test is one in which the home user draws the blood, administers

54 Fed. Reg. 7279 (February 17, 1989).

6 *The Gray Sheet*. 3 (March 20, 1989).

~ Applications for AIDS Home Test Kits, FDA Talk Paper NO. T90-20 (April 30, 1990).

8 *The Gray Sheet*, 9 (April 30, 1990).

~ Letter from FDA to University Hospital Laboratories (August 6, 1990).

the test, and interprets the results, serious concerns about reliability and effectiveness are justified. For example, the public has difficulty correctly using and reading home pregnancy tests. ~ Laboratory technicians undergo considerable training before conducting and interpreting AIDS tests—it is not as simple as mixing two test tubes and noting the color. If the test was made more rugged to accommodate the inexperience of home users as is sometimes done with other home test kits, reliability and accuracy may be sacrificed.

If the AIDS home test is simply a blood collection mechanism, however, test performance concerns are lessened. Once the blood specimen is collected, it can be mailed to a laboratory where the standard ELISA screening test and confirmatory Western Blot test can be applied just as if the sample had come from a public clinic. With a blood collection device, the reliability and effectiveness concerns are limited to issues of collection and transportation: Can a member of the general public collect a blood sample safely and get it to the laboratory in good condition? There are other home test kits currently on the market that require the user to collect a blood sample, so the prospect cannot be casually dismissed. Strict labeling and instruction requirements which take into account the abilities of different socioeconomic groups would be necessary. Most proposals for AIDS home kits employ the fingerprick method, however, some scientists have raised questions regarding the public's ability to collect an uncontaminated specimen using this method.' Further speculation has been broached about the possibility of transmitting the AIDS virus to other household members via discarded materials from the test. To counter this concern some AIDS home tests proposals included instructions to mail the used lancet with the blood sample. But the risk of contracting AIDS from a discarded lancet surely cannot be any greater than that from normal daily activities. Public health officials have gone out their way to assure the public that AIDS is not transmitted through daily household contact.

10 Testimony of Stephen Bowen, M.D., Deputy Director for AIDS and HIV in the Center for Prevention Studies at the Center for Disease Control , Open public meeting on Blood Collection Kits labeled for Human Immunodeficiency Virus Type I Antibody Testing, 48 (April 6, 1989).

~ *The Gray Sheet*, 6 (May 15, 1989).

Once the blood sample is collected, can it be safely and securely transported to the testing laboratory? Postal workers have expressed concern about the mailing of potentially HIV-infected blood. Their apprehension is misplaced, however, because large quantities of blood and medical specimens are mailed everyday. The solution is to require packaging sufficient to allay fears of possible contamination and to train postal workers in the handling of medical specimens. Transportation concerns are further minimized by the emergence of a filter paper technology employed by some AIDS home test kit proposals. Rather than submitting a vial of blood for testing (which raises further questions about freshness and shipping delays), the user mails a dried blood sample captured on filter paper.

Even with a blood collection device, the problems of false positives and negatives remain. When a test is less than 100% sensitive, some people who have the disease will not test positive—these are false negatives. When a test is less than 100% specific, some people who do not have the disease will test positive—these are false positives. With a home test kits, false positives pose the greatest problems. First, the predictive values of the AIDS tests are influenced by the prevalence of the disease in the test population. Thus, the lower the number of truly infected people in a population, the higher the number of false positives that will register. Because of false positives, it is standard procedure for laboratories to subject all positive results to a confirmatory test. Only if the second test also yields a positive result is the person notified that they are HIV positive. Any AIDS home test of the blood collection nature can easily follow the confirmatory test procedure. Of perhaps greater concern is the psychological consequences inflicted on people who falsely test positive. Yet this issue must be addressed in both traditional and home testing situations and will be considered below in the discussion of counseling.

Finally, laboratories that conduct AIDS tests are subject to quality control standards and postmarket surveillance to insure accuracy and reliability. When an inexperienced, one-time home user is conducting the test, the need for quality control is, if anything,

greater. Still, the premarket approval requirement insures that the tests meet certain standards. The FDA can monitor and regulate the manufacturer of the test and the actual testing laboratory. Further, the FDA has a Medical Device Reporting program which requires the makers of all medical devices to report all adverse effects. Unfortunately, there is usually poor postinmarket monitoring of home test kits, largely because consumers do not report all incidents to the makers. yet the FDA still allows many home diagnostics to remain on the market.

Confidentiality: One of, if not *the* central reason offered for the marketing of an AIDS home test kit is that many people who would not otherwise be tested would purchase such a kit. Behind this analysis are the confidentiality concerns repeatedly expressed by the public. AIDS activists and public health officials. In one survey, a third of those who want to be tested for AIDS say they will do so only with a home test because they do not believe other methods guard their anonymity. About sixty percent of those surveyed said they would prefer a home test over going to a doctor of clinic.^{t2} People are afraid that employers, insurers, landlords will discover their serostatus and discriminate against them. Others, especially members of groups such as racial minorities and homosexuals who have historically been discriminated against, fear mandatory public health reporting requirements.

To address these confidentiality concerns public health officials instituted confidential and anonymous testing centers across the country. Yet now, confidentiality justifications for an AIDS home test are dismissed by many parties, who point to the public clinics as sufficient. Although most people do have access through either the public or private sector to AIDS testing, the question is more appropriately whether people, particularly those in high-risk groups, actually take advantage of these resources, and if

12 Gladwell, Malcolm, FDA May Allow AIDS Home Tests, *The Washington Post* (April 25, 1990).

not, whether they would purchase an AIDS test they could administer in the privacy of their home. At a minimum, this issue warrants research.

Ironically, at the same time that confidentiality concerns are deemed illegitimate, fears that confidentiality will be breached with home tests are used to reject them. Current home test proposals envision a system where the client calls the testing center anonymously, using a coded number to receive their results. Although someone might secure the number and use it to obtain another's results, the possibility of paper falling into the wrong hands exists even when a person is notified through traditional channels. Actually, the primary breach of confidentiality most frequently comes from the individual herself. Because home users may fail to appreciate the risks of sharing their serostatus, there should be counseling on this matter.

Counseling: Probably the most controversial aspect of home testing for AIDS is over counseling. Knowledge of one's serostatus is useless without accompanying information about what it means. There is little disagreement that counseling is necessary (1) to help an individual decide whether to take an AIDS test, (2) to help an individual cope with the immediate psychological reactions to the test results, which frequently include suicide ideation or attempts, (3) to provide information about behavior changes and partner notification, and (4) to refer the individual to medical and support services. All publicly funded clinics must provide extensive face-to-face counseling both before administering an AIDS test and when reporting the results. Similarly, counseling in conjunction with an AIDS test is a part of the accepted standard of care in the medical profession, although it is not always given in the private sector.

Given that counseling is an accepted component of AIDS testing, can it be provided in the context of home tests? In addition to the information booklet and toll free numbers that would be included with a home test kit, telephone counseling is provided when the user calls in for the results. Advocates of prohibiting the use of AIDS home test kits claim that face-to-face counseling is the only appropriate method in the circumstances. They

argue that to be effective a counselor must gauge an individual's needs partly through reliance on techniques such as maintaining eye contact and reading body language, and also through a knowledge of what result they expect and the social network on which they can draw. Opponents also question whether counselors at a national telephone center can direct individuals to the appropriate local services.

Dismissing telephone counseling out of hand, however, is premature and presumptive. First, the true test of any counseling is the quality, not merely the context. Second, the question cannot be intelligently resolved without a comparison between face-to-face and telephone counseling in the context of HIV counseling. Currently, no such controlled studies have been conducted.

Finally, not only might the telephone be just as effective as face-to-face counseling, but it may be superior in some regards for certain people. First, calling for help or information can be a potentially frightening experience associated with feelings of helplessness. The telephone can enable contact on non-threatening terms. Second, the telephone offers anonymity which can facilitate greater self-revelation and openness. The anonymity may also ease fears of vulnerability, thereby opening the door to testing. The counselor is anonymous as well, allowing the client to make of the counselor what he or she needs. Third, the telephone can bridge geographic and bureaucratic barriers. The telephone allows an individual to seek help or information without having to run the gauntlet of bureaucratic procedures (appointments, waiting lists, information disclosure) which are necessary for the orderly running of an agency or clinic.

Thirty-six states have rigorous informed consent laws for AiDS testing.¹³ Although a home test would be presumptively voluntary, the decision to take the test may not be fully informed because pretest counseling would not be mandatory, even when available (unless the kits were mail order). Thus, the information booklet would have to be comprehensive and comprehensible.

13 Burns, *supra* note 1.

Changing Behavior and Promoting the Public Health: At the heart of the debate over AIDS home test kits lie ideas and beliefs about how to change people's behavior and how to best promote the public health, although these are not always made explicit. Phrased another way, would a home test kit enhance the public health efforts in the fight against AIDS'?

One argument for requiring that AIDS tests be administered only in professional health care settings is that for many people, especially racial minorities and intravenous drug users, the test may be their only avenue into the health care system. AIDS testing provides a unique opportunity for essential medical and social services to be introduced to disadvantaged individuals. This argument rests on an assumption that an AIDS home test would draw clients away from public clinics. However, it is at least possible that a home test would reach people who are already avoiding the clinics. (Many people will undoubtedly still prefer a free AIDS test in a medical setting to a home kit that must be purchased for twenty to thirty dollars.) In this scenario, a person who would not have otherwise been tested may be notified by a home test that they should seek medical attention, thereby facilitating their entrance into the health care system.

A related concern is that an AIDS home test kit would become a substitute for doctors. Medical professionals emphasize that rendering a diagnosis requires more than a test result—doctors use clinical impressions, medical history and a variety of laboratory tests when making a diagnosis. Doctors fear that an AIDS home test might encourage detrimental self treatment. On the other hand, home tests may be a viable means of increasing consumer involvement in their own health—a complement to professional care rather than a substitute.

Although there is no federal reporting requirement for HIV positive results, several states do have mandatory reporting of HIV infection. Would an AIDS home test thwart these efforts? While it would be technically possible for the laboratory to report positive results to state officials (assuming a blood collection device), the proposals to date have

said that they would not market the kits in states with mandatory reporting. A company would find it difficult to market a confidential home test if the results had to be reported to state officials.

And, the ultimate question, will AIDS home tests change people's behavior? From a public health perspective, until there is a scientific breakthrough, the only way to control the AIDS epidemic is to slow the transmission of the HIV virus which in turn requires that people alter their behavior. Will someone who tests negative with a home kit mistakenly think they are invincible and continue to engage in unsafe behavior? Will those who test positive take precautions and notify their sexual partners? Perhaps the question is better asked. is traditional AIDS testing better at securing behavioral changes?

IV. THE POLITICS OF AIDS AND THE FDA'S ROLE

The FDA is the agency responsible for protecting the public's health.

The above proposition may initially appear sufficient to resolve the debate generated by AIDS home test kits. If medical devices such as AIDS home test kits are detrimental to the public health, the FDA should keep them off the market. But once you begin unpacking the term public health. the difficult questions proliferate. What is the public health? Who is the public? How is the FDA supposed to assess the public health?

Under § 513(a)(2)(C) of the Medical Device Amendment, the FDA must find a medical device safe and effective using a risk/benefit analysis. Safety and effectiveness are determined by weighing the probable benefit to health against the probable risk of injury or illness—a standard purposely less stringent than that applied to drugs. The statute does not tell us, however, whose benefit—individual or societal. The debate over AIDS home tests has appropriately considered whether an individual can safely and effectively use the kits. Thus, the FDA has asked whether the public can collect blood samples and whether the test yields accurate results.

But opponents of an AIDS home test suggest other criterion for the safety and effectiveness of the kits. At the subcommittee hearings, one witness deemed AIDS home test kits ineffective because he believed they would not bring about a change in risky behaviors. The same witness also found home diagnosis unsafe, arguing that it would encourage risky behavior in people testing negative.^{t4} The problem with his reasoning is that it is speculative. When assessing the impact of a new technology on public health at a macro level, the imagination reigns. I can conceive a scenario whereby the mass use of AIDS home test kits would result in millions of Americans finding out that they are negative which in turn might lead to a decrease in public support for AIDS funding which would adversely affect public health. But intuitions about human nature and American culture should not be a basis for a federal agency to limit access to a product.

Who will buy an AIDS home test? Will people change their behavior? This paper is full of question marks. The long range, broad impact of an AIDS home test kit cannot be known until the product is disseminated. Although the FDA should not ignore utility of a medical device when considering a PMA, nor should it allow speculation to control.

Further, when assessing risk, we frequently dodge the issue by using the very uncertainty at stake, replacing a probability of harm analysis with the possibility of harm. A critical value judgment being made by everyone, although usually unstated, is who should bear the burden of uncertainty. While the FDA is used to facing scientific uncertainty, the uncertainty here is also of the human sort. As Randy Shilts exhaustively documents in *And the Band Played On*, in the early days of the AIDS epidemic uncertainty became an excuse for inaction with disastrous consequences. Especially given the history of official paralysis over AIDS, when there are no immediate risks to an individual's health, the FDA should not intervene to remove choices.

14 Testimony of Jose Szapocznik, Ph.D. on behalf of American Psychological Association before the House Subcommittee on Regulation, Business Opportunities, and Energy, Risks and Implications of AIDS-HIV Testing in Nontraditional Laboratories and in the Home, 20-21 (March 23, 1989).

One reason the FDA is now willing to consider the possibility of AIDS home test kits is that it finally examined the product from a medical perspective. Since the debate over AIDS home test kits began, the medical profession has become increasingly convinced of the value of early diagnosis. Early diagnosis is important at a societal level in controlling the transmission of the virus and it is also critical to providing the best medical care to infected individuals. There are now drugs such as AZT which may prolong the onset of the disease. Federal health officials just released new guidelines covering early preventative treatments of HIV disease.¹⁵ If an AIDS home test kit might encourage early diagnosis, then its value should not be obscured by endless debates over telephone versus face-to-face counseling that too much resemble turf wars.

Even though it is private industry pushing for home diagnosis, with some creative thinking the government may be able to also effectively use the product. For example, the government could give away free home test kits to people in high risk communities. The AIDS home test kit is not a universal strategy, but it may be one part of the solution in the fight against AIDS.

Finally, although I am in favor of permitting an AIDS home test to market, I want to consider a more fundamental question: Why would people even want to take an AIDS test in their home? The debate over AIDS home test kits is a product of what some have termed AIDS exceptionalism. AIDS has been classified differently and exempted from more traditional approaches to epidemics which have historically emphasized identification of the infected. One reason may be that this is the first major epidemic since civil liberties achieved paramount importance in American jurisprudence. The central feature of AIDS which makes our society so uncomfortable is its transmission through intimate activities such as sexual relations and childbirth. During the last several decades our constitutional law tradition and our social ethos have stressed the importance of

¹⁵ Learv, Warren, U.S. Offers Guide for Doctors On Care of those With H.I.V., *New York Times*. A2 1 (January 21, 1994).

privacy, especially with regard to intimate associations. Thus, AIDS generates a tension, if not a collision, between the ethos of public health and civil liberties. While public health takes the communal well-being as the fundamental good, civil liberties places individual freedom at the pinnacle. The challenge is to translate the tension between these abstract notions into a response to a particular disease.

AIDS home test kits are a logical extension of the tremendous emphasis placed on privacy and civil liberties in this epidemic. Regardless of whether you value public health or civil liberties more, the language of privacy may have obscured the analysis with talk of rights and balancing: a crisis and a 'reasonable' balance rarely coexist. I wonder if secrecy is a sensible way to confront an epidemic. The voluntarist consensus which is premised on the stigma surrounding AIDS may only serve to reinforce it.

My point is not that policy makers should banish value decisions in favor of a scientific approach to AIDS; there cannot be an apolitical public health policy. Rather, decisions about HIV policy will always reflect the balance of moral and political commitments to privacy, reason, and public health and thus will have a fundamental impact on the social context in which HIV disease will be transmitted and confronted. Yet it may be time to reverse the question and ask what are the scientific limits on our political ideology.